DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0234]

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual guidance document agenda. FDA committed to publishing, on an annual basis, a list of possible topics for future guidance document development or revision during the next year, and seeking public comment on additional ideas for new guidance documents or revisions of existing ones. This commitment was made in FDA's September 2000 good guidance practices (GGPs) final rule, which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to seek public comment on possible topics for guidance documents and possible revisions to existing guidances.

DATES: Submit written or electronic comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

For general information regarding this list contact: Diane Sullivan, Office

of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

For information regarding specific topics or guidances: Please see contact persons listed in the table in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 2000 (65 FR 56468), FDA published a final rule announcing its GGPs, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGPs to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publishing an annual guidance document agenda of possible guidance topics or documents for development or revision during the coming year. The agency also committed to soliciting public input regarding these and additional ideas for new topics or revisions to existing guidance documents (65 FR 56468 at 56477, 21 CFR 10.115(f)(5)).

The agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the agency is considering. The agency solicits comments on the topics listed in this document and also seeks additional ideas from the public.

The guidance documents are organized by the issuing center or office within FDA, and are further grouped by topic categories. The agency's contact persons are listed for each specific area in the table.

TITLE/TOPIC OF GUIDANCE	CONTACT
II. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)	
CATEGORY—COMPLIANCE AND INSPECTION	
Reprocessing, Reworking, and Blending of Biological Drug Substances and Drug Products	Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.
Design, Installation and Operation of Heating, Ventilation and Air Conditioning Systems Used in the Manufacture of Products Regulated by the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research	Same as above (Do)
Compliance Program 7341.002—Inspection of Tissue Establishments	Do
Compliance Program 7342.001—Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors	Do
Compliance Program 7342.002—Inspection of Source Plasma Establishments	Do
Compliance Program 7342.008—Inspections of Licensed Viral Marker Test Kits	Do
Compliance Program 7345.001—Inspection of Center for Biologics Evaluation and Research-Regulated Biological Drug Products	Do
CATEGORY—CELLULAR, TISSUE, AND GENE THERAPY	
Submission of Information for the National Xenotransplantation Database	Do
Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Controls Reviewers of Human Gene Therapy Investigational New Drug Applications	Do
Submission of Information for Adverse Event and Annual Reports for Gene Therapy Investigational New Drug Applications	Do
Eligibility Determination for Donors of Human Cells, Tissue and Cellular and Tissue-Based Products	Do
CATEGORY—BLOOD AND BLOOD COMPONENTS	
Blood Establishment Software	Do
Collection of Platelets, Pheresis Prepared by Automated Methods	Do
Validation of the Computer Crossmatch	Do
Blood Contact Materials	Do
Nucleic Acid Testing for Human Immunodeficiency Virus and Hepatitis C Virus; Testing, Product Disposition, Donor Deferral and Re-entry	Do
Efficacy, Pharmokinetic, and Safety Studies to Support Marketing of Immune Globulin Intravenous (Human) as a Replacement Therapy for Primary Humoral Immunodeficiency	Do
Guidance on the Content of Premarket Submissions for Center for Biologics Evaluation and Research-Regulated Automated Instruments and Associated Software Systems for Donor Blood Collection and Screening	Do
CATEGORY—VACCINES	
Characterization and Qualification of Cell Substances and Viral Seeds Used to Produce Viral Vaccines	Do
Preclinical Toxicity Studies for Prophylactic Vaccines	Do
Immunization Human Plasma Donors to Obtain Source Plasma for Preparation of Specific Immune Globulins	Do
Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for a Vaccine or Related Product	Do
Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
CATEGORY—OTHER	
Providing Regulatory Submission in Electronic Format—Stability	Do
Environmental Assessment/National Environmental Policy Act	Do
Filing and Application When the Applicant Protests a Refusal to File Action	Do
Multi-Product Manufacturing With Spore-Forming Microorganisms	Do
Good Review Practices—Track IV	Do
Submission of Chemistry, Manufacturing, and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products	Do
Submission of Chemistry, Manufacturing, and Control Information for a Therapeutic Recombinant Deoxyribonucleic Acid-Derived Product or a Monoclonal Antibody for In-Vivo Use	Do
III. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	
Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff and Third Parties	John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–0806
Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties	Do
Mutual Recognition Agreement Between the European Union and the United States of America: Confidence Building Programme: Overview and Procedure; Medical Device Annex, Version 7, June 29, 2000; Draft	Christine Nelson, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–0806
Regulation of Medical Devices; Background Information for International Officials (Entire Document Available on Disk)	Ron Parr, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–0806
Guidance for Staff, Industry, and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community	John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–0806
Medical Device Appeals and Complaints: A Guidance on Dispute Resolution	Do
Overview of Food and Drug Administration Modernization Act of 1997 Medical Device Provisions (Food and Drug Administration Modernization Act)	Do
Medical Device Reporting for Manufacturers	Do
In Vitro Diagnostic Devices: Guidance for the Preparation of Premarket Notification Submissions (FDA 97–4224)	Do
Medical Device Quality Systems Manual: A Small Entity Compliance Guide	Do
Comparison Chart: 1996 Quality System Reg vs. 1978 Good Manufacturing Practices Reg vs. ANSI/ISO/ASQC Q9001 and ISO/DI 13485:1996 (Include 126)	Do
Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices (FDA 95–4158)	Do
Labeling—Regulatory Requirements for Medical Devices (FDA 89–4203)	Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1217
Impact Resistant Lenses: Questions and Answers (FDA 87–4002)	Do
Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use (Draft)	Lily Ng, Center for Devices and Radiological Health (HFZ–510), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–0885
Frequently Asked Questions About the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions	Do
Frequently Asked Questions About the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff	Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1217
Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers	Do
Center for Devices and Radiological Health Manual for the Good Guidance Practices Regulations; Final Guidance for FDA Staff	Ron D. Kaye, Center for Devices and Radiological Health (HFZ–205), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3265
Medical Device Use—Safety: Incorporating Human Factors Engineering Into Risk Management; Guidance for Industry and FDA Premarket and Design Control Reviewers	Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1217

TITLE/TOPIC OF GUIDANCE	CONTACT
Human Factors Points to Consider for Investigational Device Exemption Devices	Alvin W. Thomas, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2436
Do It By Design—An Introduction to Human Factors in Medical Devices	Walter I. Scott, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3266
Medical Device Reporting for User Facilities	Margaret T. Tolbert, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2436
Human Factors Principles for Medical Device Labeling	Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1217
Write It Right	Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3332
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #8 (Incorporated into Policy Guidance Help Systems)	Do
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #7; Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #5; Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #4; Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
Compliance Guidance—The Mammography Quality Standards Act Final Regulations—Preparing for Mammography Quality Standards Act Inspections (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #3; Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations Modifications to the Policy Guidance Help System Due to the September 11, 2001, Terrorist Attacks; Final Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #4; Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations; Modifications and Additions to Policy Guidance Help System #2; Final Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
Compliance Guidance—Mammography Facility Survey, Equipment Evaluation and Medical Physicist Qualification Requirements Under MQSA; Final (Incorporated into Policy Guidance Help System)	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3 (Incorporated into Policy Guidance Help System)	Do
The Mammography Quality Standards Act Final Regulations Modifications to the Policy Guidance Help System #1; Guidance for Industry and FDA (Incorporated into Policy Guidance Help System)	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2 (Incorporated into Policy Guidance Help System)	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Quality Assurance Documentation (Incorporated into Policy Guidance Help System)	Do
Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities Under the Mammography Quality Standards Act (42 U.S.C. 263(b)) (Incorporated into Policy Guidance Help System)	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly (Incorporated into Policy Guidance Help System)	Do
Guidance: The Mammography Quality Standards Act Final Regulations Document #1 (Incorporated into Policy Guidance Help System)	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance for Industry—Requalification for Interpreting Physician's Continuing Experience Requirement (Incorporated into Policy Guidance Help System)	Do
Policy and Standard Operating Procedures When Mammography Facilities in States That Have Accreditation Bodies Intend to Change Accreditation Bodies (Incorporated into Policy Guidance Help System)	Do
Guidance for Review of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act (42 U.S.C. 263(b)) (April 8, 1998) (Incorporated into Policy Guidance Help System)	Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1217
Guidance for Submission of Request for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Acts (42 U.S.C. 263(b)) (April 8, 1998) (Incorporated into Policy Guidance Help System)	Do
Continuing Education Credit for Reading/Writing Articles/Papers and Presenting Courses/Lectures (Incorporated into the Policy Guidance Help System)	Do
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies	Thomas E. Cardamone, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–0806, ext. 117
Office of Device Evaluation	
Fiscal Year 2004 MDUFMA Small Business Qualification Worksheet and Certification—Guidance for Industry and FDA	Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Premarket Assessment of Pediatric Medical Devices—Draft Guidance for Industry and FDA Staff	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Pediatric Expertise for Advisory Panels—Guidance for Industry and FDA Staff	Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Premarket Approval Application Filing Review—Guidance for Industry and FDA Staff	Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Guidance for Industry and FDA: Fiscal Year 2003 MDUFMA Small Business Qualification Worksheet and Certification	Do
Assessing User Fees: Premarket Approval Application Supplement Definitions, Modular Premarket Approval Application Fees, Biologics License Application and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products	Do
Determination of Intended Use for 510(k) Devices; Guidance for Center for Devices and Radiological Health Staff	Do
The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles: Final Guidance for FDA and Industry	Thninh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186
Updated 510(k) Sterility Review Guidance K90–1; Final Guidance for Industry and FDA	Robert R. Gatling, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Availability of Information Given to Advisory Committee Members in Connection With Center for Devices and Radiological Health Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff	Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022
Humanitarian Device Exemptions Regulation: Questions and Answers; Final Guidance for Industry	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and Center for Devices and Radiological Health Staff	Donna-Bea Tillman, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022
Early Collaboration Meetings Under the FDA Modernization Act; Final Guidance for Industry and for Center for Devices and Radiological Health Staff	Do
Deciding When to Submit a 510(k) for a Change to an Existing Wireless Telemetry Medical Device; Final Guidance for FDA Reviewers and Industry	Karen F. Warbuton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744
Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997	Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance on Amended Procedures for Advisory Panel Meetings; Final	Daniel G. Schultz, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022
Guidance on the Use of Standards in Substantial Equivalence Determinations; Final	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Guidance for Off-the-Shelf Software Use in Medical Devices; Final	Joanna H. Weitershausen, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8611
Medical Devices Containing Materials Derived From Animal Sources (Except In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry; Final	Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186
Premarket Approval Application Modular Review	Philip J. Phillips, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022
Guidance for Industry; General/Specific Intended Use; Final	Thninh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186
Frequently Asked Questions on the New 510(k) Paradigm; Final	Do
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final	Do
Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review; Final	Do
A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications	Do
Guidance for Industry and FDA Staff: Expedited Review of Premarket Submissions for Devices	Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
PMA/510(k) Expedited Review G94–4 (blue book memo)	Thninh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186
30-Day Notices and 135-Day Premarket Approval Application Supplements for Manufacturing Method or Process Changes, Guidance for Industry and Center for Devices and Radiological Health (Docket 98D–0080); Final	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Guidance on Premarket Approval Application Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by Center for Devices and Radiological Health and Industry; Final	Thninh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186
New Section 513(f)(2)—Evaluation of Automatic Class III Designation: Guidance for Industry and Center for Devices and Radiological Health Staff; Final	Do
Procedures for Class II Device Exemptions From Premarket Notification Guidance for Industry and Center for Devices and Radiological Health Staff; Final	Do
Guidance on Investigational Device Exemption Policies and Procedures; Final	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages	Do
Kit Certification for Premarket Notifications	Do
Convenience Kits Interim Regulatory Guidance	Do
Real-Time Review Program for Premarket Approval Application Supplements	Do
Deciding When to Submit a Premarket Notification for a Change to an Existing Device (K97–1)	Do
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	Do
Memorandum of Understanding Regarding Patient Labeling Review (blue book memo #G96–3)	Do
Continued Access to Investigational Devices During Premarket Approval Application Preparation and Review (blue book memo) (D96–1)	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Format for Investigational Device Exemption Progress Reports	Do
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance	Do
Premarket Notification Quality Review Program (blue book memo)	Do
Suggested Content for Original Investigational Device Exemption Application Cover Letter	Do
Indications for Use Statement	Do
Cover Letter: Premarket Notification Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (blue book memo #K95–1)	Do
#D95–2, Attachment A (Interagency Agreement Between FDA & Health Care Financing Administration	Do
#D95–2, Attachment B (Criteria for Categorization of Investigational Devices Health Care Financing Administration	Do
Health Care Financing Administration Reimbursement Categorization Determinations for FDA-Approved Investigational Device Exemptions	Do
Implementation of the FDA/Health Care Financing Administration Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Attachment A Interagency Agreement, Attachment B Criteria for Categorization of Investigational Devices, and Attachment C -List #D95–2 (blue book memo)	Do
Goals and Initiatives for the Investigational Device Exemption Program #D95–1 (blue book memo)	Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Memorandum: Electromagnetic Compatibility for Medical Devices: Issues and Solutions	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Use of International Standard ISO–10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing7rsquo; (Replaces #G87–1 #8294) (blue book memo)	Do
Premarket Approval Application Closure #P94–2 (blue book memo)	Do
Premarket Notification Sign-Off Procedures #K94–2 (blue book memo)	Do
Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer From Susan Alpert	Do
Premarket Notification Refuse to Accept Procedures #K94–1 (blue book memo)	Do
Investigational Device Exemption Refuse to Accept Procedures #D94–1 (blue book memo)	Do
Preamendments Class III Strategy Premarket Notification Status Request Form	Do
Documentation and Resolution of Differences of Opinion on Product Evaluations #G93–1 (blue book memo)	Do
Premarket Notification Additional Information Procedures #K93–1 (blue book memo)	Do
Center for Devices and Radiological Health's Investigational Device Exemption Refuse to Accept Policy	Do
Center for Devices and Radiological Health's Premarket Notification Refuse to Accept Policy—(Updated Checklist for March 14, 1995)	Do
Classified Convenience Kits	Do
Telephone Communications Between Office of Device Evaluation Staff and Manufacturers #I93–1 (blue book memo)	Do
Preamendment Class III Devices	Do
Nondisclosure of Financially Sensitive Information #I92–1 (blue book memo)	Do
Document Review Processing #I91–1 (blue book memo)	Do
Integrity of Data and Information Submitted to Office of Device Evaluation #I91–2 (blue book memo)	Do
Panel Review of Premarket Approval Applications #P91–2 (blue book memo)	Do
Premarket Approval Application Compliance Program #P91–3 (blue book memo)	Do
Shelf Life of Medical Devices	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Device Labeling Guidance #G91–1 (blue book memo)	Do
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices #G90–2 (blue book memo)	Do
Consolidated Review of Submissions for Lasers and Accessories #G90–1 (blue book memo)	Do
Assignment of Review Documents #I90–2 (blue book memo)	Do
Policy Development and Review Procedures #I90–1 (blue book memo)	Do
Substantial Equivalence Decision Making Documentation ATTACHED: 'SE' Decision Making Process (Detailed) (i.e., the decision making tree)	Do
Threshold Assessment of the Impact of Requirements for Submission of Premarket Approval Applications for 31 Medical Devices Marketed Prior to May 28, 1976	Do
Meetings With the Regulated Industry #I89–3 (blue book memo)	Do
Toxicology Risk Assessment Committee #G89–1 (blue book memo)	Do
Review of IDEs for Feasibility Studies #D89–1 (blue book memo)	Do
Premarket Notification—Consistency of Reviews #K89–1 (blue book memo)	Do
Review of Laser Submissions #G88–1 (blue book memo)	Do
Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test	Do
Limulus Amebocute Lysate; Reduction of Samples for Testing	M. Sussan Runer, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283
Master Files Part III; Guidance on Scientific and Technical Information	Do
Guideline on General Principles of Process Validation	Do
Industry Representatives on Scientific Panel	Do
Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program #K86–3 (blue book memo)	Do
Panel Report and Recommendations on PMA Approvals #P86–5 (blue book memo)	Do
Points to Consider in the Characterization of Cell Lines Used to Produce Biological Products	Do
Application of the Device Good Manufacturing Practice Regulation to the Manufacture of Sterile Devices	Do
Methods for Conducting Recall Effectiveness Checks	Do
Guidance for Submitting Reclassification Petition	Do
Guidance for Industry and FDA: User Fees and Refunds for Premarket Approval Applications	Do
Bundling Multiple Devices or Multiple Indications in a Single Submission—Guidance for Industry and FDA Staff	Do
FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment	Do
Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; Draft	Do
Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA	Do
Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCo_2$ and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA	Do
Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA	Do
Heated Humidifier Review Guidance	Do
Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing of Dental Restorations; Guidance for Industry and FDA	Anthony Watson, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–824–1287
Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA	Do
Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Guidance for Industry and FDA Reviewers	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA	Do
Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants; Final	Do
Guidance for the Preparation of Premarket Notifications for Dental Composites	Do
Dental Cements—Premarket Notification; Final	Do
Dental Impression Materials—Premarket Notification; Final	Do
Over-the-Counter Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits; Final	Do
Information Necessary for Premarket Notification Submissions for Screw-Type Endosseous Implants	Kevin Mulry, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283
Guidance Document on Dental Handpieces	Do
Guidance for the Arrangement and Content of a Premarket Approval Application for an Endosseous Implant for Prosthetic Attachment	Do
Premarket Notification Submissions for Chemical Indicators; Guidance for Industry and FDA Staff	Do
Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Precious Metal Alloys	Do
Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Base Metal Alloys	Do
Supplementary Guidance on Premarket Notifications for Medical Devices With Sharps Injury Prevention Features; Guidance for Industry and FDA	Do
Guidance on Premarket Notifications for Intravascular Administration Sets	Do
Neonatal and Neonatal Transport Incubators—Premarket Notifications; Final	Do
Guidance on the Content of Premarket Notification Submissions for Protective Restraints	Do
Guidance on Premarket Notification Submissions for Short-Term and Long-Term Intravascular Catheters	Do
Guidance on the Content of Premarket Notification Submissions for Hypodermic Single Lumen Needles	Do
Guidance on the Content of Premarket Notification Submissions for Piston Syringes	Do
Guidance on the Content of Premarket Notification Submissions for Clinical Electronic Thermometers	Do
Guidance on the Content of Premarket Notification Submissions for External Infusion Pumps	Do
Guidance on Premarket Notification Submissions for Implanted Infusion Ports	Do
Surgical Masks—Premarket Notification Submissions; Draft Guidance	Bram D. Zuckerman, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320
Regulatory Status of Disinfectants Used to Process Dialysate Delivery Systems and Water Purification Systems for Hemodialysis; Guidance for Industry and FDA	Do
Premarket Notification Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA	Do
Premarket Notifications for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers	Elias Mallis, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517
Premarket Approval Applications for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA	Do
Guidance on the Content and Format of Premarket Notification Submissions for Liquid Chemical Sterilants and High Level Disinfectants; Final	Do
Premarket Notification Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products; Final	Do
Center for Devices and Radiological Health Regulatory Guidance for Washers and Washer-Disinfectors Intended for Use in Processing Reusable Medical Devices	Do
Testing for Sensitizing Chemicals in Natural Rubber Latex Medical Devices (Addendum to 944)	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Addendum to: Guidance on Premarket Notification Submissions for Sterilizers Intended for Use in Health Care Facilities	Dina Fleisher, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517
Guidance on the Content and Format of Premarket Notification Submissions for Sharps Containers	Do
Guidance on Premarket Notification Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	Do
Guidance on Premarket Notification Submissions for Surgical Gowns and Surgical Drapes	Do
Guidance on Premarket Notification for Sterilizers Intended for Use in Health Care Facilities	Ashley Boam, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243
Battery Guidance	Megan Moynaham, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517
Policy for Expiration Dating (DCRND RB92–G)	Do
Balloon Valvuloplasty Guidance for the Submission of an Investigational Device Exemption Application and a Premarket Approval Application	A. Doyle Gantt, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262
Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm	Do
Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry	Do
Investigational Device Exemption Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers	Do
Recommended Clinical Study Design for Ventricular Tachycardia Ablation	Neil R. Ogden, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1307
Nonautomated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1; Final	Do
Noninvasive Blood Pressure Monitor Guidance	Do
Electrocardiograph Electrode	Do
Electrocardiograph Lead Switching Adapter	Do
Electrocardiograph Surface Electrode Tester	Do
Clinical Study Designs for Percutanwous Catheter Ablation for Treatment of Atrial Fibrillation—Guidance for Industry and FDA Staff	Do
Guidance for Annuloplasty Rings Premarket Notification Submissions; Final Guidance for Industry and FDA Staff	Barbara Zimmerman, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter Premarket Notification Submissions; Final Guidance for Industry and FDA	Do
Guidance for Extracorporeal Blood Circuit Defoamer Premarket Notification Submissions; Final Guidance for Industry and FDA	Do
Guidance for Cardiopulmonary Bypass Oxygenators Premarket Notification Submissions; Final Guidance for Industry and FDA Staff	Do
Guidance for the Preparation of the Annual Report to the Premarket Approval Application Approved Heart Valve Prostheses	Do
Coronary and Cerebrovascular Guidewire Guidance	Do
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor Premarket Notification Submissions	Do
Implantable Pacemaker Testing Guidance	Do
Guidance Document for Vascular Prostheses Premarket Notification Submissions	Do
Guidance for Cardiovascular Intravascular Filter Premarket Notification Submissions; Final	Do
Carotid Stent—Suggestions for Content of Submissions to the Food and Drug Administration in Support of Investigational Devices Exemption Applications	Do
Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices—Draft Guidance for Industry and FDA Staff	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance Document for Powered Suction Pump Premarket Notifications	Steven Rhodes, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090
Guidance Document for Surgical Lamp Premarket Notification; Final	Do
Guidelines for Reviewing Premarket Notifications That Claim Substantial Equivalence to Evoked Response Stimulators	Do
Guidance Document for the Preparation of Premarket Notification Applications for Electromyograph Needle Electrodes	Do
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	Do
Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices	Do
Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA	Do
Class II Special Controls Guidance Document: Polymethylmethacrylate Bone Cement; Guidance for Industry and FDA	Do
Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis	Theodore R. Stevens, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296
Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semiconstrained Porous-Coated Uncemented Prosthesis Guidance for Spinal System Premarket Notifications	Do
Guidance Document for the Preparation of Investigational Device Exemptions for Spinal Systems	Do
ORDB Premarket Notification Sterility Review Guidance	Do
Reviewers Guidance Checklist for Intramedullary Rods	Do
Reviewers Guidance Checklist for Orthopedic External Fixation Devices	Do
Premarket Notification Information Needed for Hydroxyapatite Coated Orthopedic Implants	Do
Guidance Document for Testing Biodegradable Polymer Implant Devices	Do
Guidance Document for Testing Bone Anchor Devices	Do
Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components	Do
Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems	Do
Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement	Do
Guidance Document for the Preparation of Investigational Device Exemption and Premarket Approval Applications for Intra-Articular Prosthetic Knee Ligament Devices	Do
Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA	Evertte T. Bears, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018
Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA	Do
Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA	Do
Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry	Do
Guidance Document for Dura Substitute Devices; Final Guidance for Industry	Do
Guidance for Neurological Embolization Devices	Do
Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater; Final	Do
Guidance for Dermabrasion Devices; Final	Do
Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final	Do
Guidance for Content of Premarket Notifications for Esophageal and Tracheal Prostheses; Final	Eric A, Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080
Guidance for Testing Magnetic Resonance Interaction With Aneurysm Clips	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA	Do
Cyanoacrylate Tissue Adhesive for the Topical Approzimation of Ski—Premarket Approval Applications—Guidance for Industry and FDA Staff	Do
Saline, Silicone Gel, and Alternative Breast Implants—Draft Guidance for Industry	Kesia Alexander, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053
Guidance Document for Powered Muscle Stimulator Premarket Notifications; Final	
Guidance Document for the Preparation of Premarket Notification Applications for Therapeutic Massagers and Vibrators	Do
Guidance Document for the Preparation of Premarket Notification Applications for Beds	Do
Guidance Document for the Preparation of Premarket Notification Applications for Communications Systems (Powered and Nonpowered) and Powered Environmental Control Systems	Do
Guidance Document for the Preparation of Premarket Notification Applications for Exercise Equipment	Do
Guidance Document for the Preparation of Premarket Notification Applications for Heating and Cooling Devices	Do
Guidance Document for the Preparation of Premarket Notification Applications for Immersion Hydrobaths	Do
Guidance Document for the Preparation of Premarket Notification Applications for Powered Tables and Multifunctional Physical Therapy Tables	Carolyn Y. Neuland, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220
Guidance Document for the Preparation of Premarket Notification Applications for Submerged (Underwater) Exercise Equipment	Do
Guidance Document for the Preparation of Premarket Notification Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	Do
Guidance for Studies for Pain Therapy Devices—General Consideration in the Design of Clinical Studies for Pain-Alleviating Devices	Do
Guidance Document for Nonprescription Sunglasses; Final Ophthalmoscope Guidance	Do
Retinoscope Guidance; Final	Do
Slit Lamp Guidance; Final	Do
Third Party Review Guidance for Phacofragmentation System Device Premarket Notification	Do
Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification	Collin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180
Checklist of Information Usually Submitted in an Investigational Device Exemptions Application for Refractive Surgery Lasers (Excimer)	Do
Implantable Middle Ear Hearing Device; Guidance for Industry and FDA	Do
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers; Final	Do
Tympanostomy Tubes, Submission Guidance for a Premarket Notification; Final	Do
Guidance For The Arrangement and Content of a Premarket Approval Application For A Cochlear Implant in Children Ages 2 to 17 Years	Do
Guideline for the Arragement and Content of a Premarket Approval Application for a Cochlear Implant in Adults at Least 18 Years of Age	Do
Guideline for the Arrangement and Content of a Premarket Approval Application for a Cochlear Implant in Adults at Least 18 Years of Age	Do
Guidance on Submissions for Keratoprostheses; Final	Do
Aqueous Shunts—Premarket Notification Submissions; Final	Do
FDA Guidelines for Multifocal Intraocular Lens Investigational Device Exemptions Studies and Premarket Approval Applications	Do
Important Information About Rophae Intraocular Lenses	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses; Final	Do
Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear; Final	Do
Premarket Notification Guidance for Contact Lens Care Products	Do
Premarket Notification Guidance Document for Class II Daily Wear Contact Lenses	Do
New FDA Recommendations and Results of Contact Lens Study (7-Day Letter)	Do
Class II Special Controls Guidance Document; Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA	Do
Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers	Janine M. Morris, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194
Guidance for Investigational Device Exemptions for Solutions for Hypothermic Flushing, Transport, and Storage of Organs for Transplantation; Final Guidance for Industry and FDA Reviewers	Do
Guidance for Industry and the Center for Devices and Radiological Health Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems; Final	Do
Guidance for the Content of Premarket Notification for Conventional and High Permeability Hemodialyzers; Final	Do
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; Final	Do
Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis	Do
Class II Special Controls Guidance Document: Breast Lesion Documentation System—Guidance for Industry and FDA Staff	Do
Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers	Do
Class II Special Controls Guidance Document for Clitoral Engorgement Devices	Do
Latex Condoms for Men—Information for Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions	Do
Uniform Contraceptive Labeling; Final	Do
Letter to Manufacturers of Prescription Home Monitors for Non-Stress Tests	Do
Letter to Manufacturers of Falloposcopes	Do
Thermal Endometrial Ablation Devices (Submission Guidance for an Investigational Device Exemption)	Do
Hysteroscopes and Gynecology Laparoscopes—Submission Guidance for a Premarket Notification	Do
Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA	Do
Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources	Do
Guidance for the Submission of Premarket Notifications for Medical Image Management Devices	Do
Guidance for the Submission of Premarket Notification for Solid State X-Ray Imaging Devices; Final	Do
Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories and Nuclear Tomography Systems; Final	Do
Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators; Final	Do
Harmonic Imaging With/Without Contrast—Premarket Notification; Final	Do
Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Final	Do
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	Do
Letter: Notice to Manufacturers of Bone Mineral Densitometers	Do
Simplified Premarket Notification Procedures for Certain Radiology Devices: December 21, 1993, Letter From L Yin, Office of Device Evaluation, Division of Reproduction, Abdominal, and Radiological Devices, to National Electrical Manufacturers Association	Avis T. Danishefsky, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1243
Reviewer Guidance for Automatic X-Ray Film Processor Premarket Notification	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance for the Content of Premarket Notifications for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi	Do
Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final	Do
Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters; Final	Do
Center for Devices and Radiological Health Interim Regulatory Policy for External Penile Rigidity Devices	Do
Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastroenterology and Urology	Do
Premarket Notification Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments	Do
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters	Do
Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	Do
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	Do
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology	Do
Guidance for the Content of Premarket Notifications for Ureteral Stents	Do
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)	Do
Premarket Approval Application Review Statistical Checklist	Do
Statistical Guidance for Clinical Trials of Nondiagnostic Medical Devices	Do
Medical Device Reporting Guidance Document: Remedial Action Exemption; Final	Do
Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use	Do
Medical Device Reporting Guidance Document No. 1—Intraocular lenses—E1996004; Final	Do
Common Problems: Baseline Reports and Medwatch Form 3500A	Do
Medical Device Reporting: An Overview; Final	Do
Instructions for Completing FDA Form 3500A With Coding Manual for Form 3500A (MEDWATCH) (Medical Device Reporting); Final	Do
MEDWATCH FDA Form 3500A For Use By User Facilities, Distributors and Manufacturers for Mandatory Reporting (Medical Device Reporting); Final	Do
Variance from Manufacturer Report Number Format (Medical Device Reporting Letter); Final	Do
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report (Medical Device Reporting); Final	Do
Medical Device Reporting—Alternative Summary Reporting Program; Guidance for Industry	Do
Addendum to the Instructions for Completing FDA Form 3500A With Coding Manual (MEDWATCH) (Medical Device Reporting); Final	Do
Needlesticks—Medical Device Reporting Guidance	Do
Guidance on Criteria and Approaches for Postmarket Surveillance	Do
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies (Food and Drug Administration Modernization Act); Final	Do
Guidance on Procedures for Review of Postmarket Surveillance Submissions (Food and Drug Administration Modernization Act); Final	Do
Guidance for Industry and FDA Staff—Safe Medical Devices Act to Food and Drug Administration Modernization Act: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols (Food and Drug Administration Modernization Act); Final	Do
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket	Do
Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)	
Analyte Specific Reagents; Small Entity Compliance Guidance; Guidance for Industry	Do
Assessing the Safety/Effectiveness of Home-Use In Vitro Diagnostic Devices: Draft Points to Consider Regarding Labeling and Premarket Submissions	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers	Do
Determination of Intended Use for Premarket Notification Devices; Guidance for the Center for Devices and Radiological Health Staff	Do
Guidance for Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization	Do
Guidance for Clinical Laboratory Improvement Amendments of 1988 Criteria for Waiver; Draft Guidance for Industry and FDA	Do
Guidance for Industry—Abbreviated Premarket Notification Submissions for In Vitro Diagnostic Calibrators; Final	Do
Letter to In-Vitro Device Manufacturers on Streamlined Premarket Approval Applications; Final	Do
Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for Premarket Notification Clearance	Do
Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter Dated March 14, 1996	Do
Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft	Do
Premarket Approval Application Filing Review—Guidance for Industry and FDA Staff	Do
Breath Nitric Oxide Test System—Class II Special Controls Guidance Document	Do
Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers	Do
Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA	Do
Draft Guidance for Prescription Use of Drugs of Abuse Assays Premarket Notifications	Do
Draft Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing	Do
Guidance for Premarket Notifications on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use	Do
Guidance for Industry In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Final	Do
Guidance for Industry In Vitro Diagnostic Chloride Test System; Final	Do
Guidance for Industry In Vitro Diagnostic Creatinine Test System; Final	Do
Guidance for Industry In Vitro Diagnostic Glucose Test System; Final	Do
Guidance for Industry In Vitro Diagnostic Potassium Test System; Final	Do
Guidance for Industry In Vitro Diagnostic Sodium Test System; Final	Do
Guidance for Industry In Vitro Diagnostic Urea Nitrogen Test System; Final	Do
Guidance for Industry-In Vitro Diagnostic C-Reactive Protein Immunological Test System	Do
Guidance for Over-the-Counter Human Chorionic Gonadotropin Premarket Notifications	Do
Guidance for Over-the-Counter Ovulation Predictor Premarket Notifications	Do
Over the Counter Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications	Do
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies	Do
Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	Do
Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin In Vitro Diagnostic Devices	Laura A. Alonge, Center for Devices and Radiological Health (HFZ–510), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–0648
Premarket Notification Submissions for Coagulation Instruments—Guidance for Industry and FDA Staff	Do
Class II Special Control Guidance Document for Anti-Saccharomyces Cerevisia (S. cerevisiae) Antibody Premarket Notifications	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA	Do
Document for Special Controls for Erythropoietin Assay Premarket Notifications; Final	Do
Draft Guidance Document for Premarket Notification Submission of Fecal Occult Blood Tests	Do
Draft Guidance Document for Premarket Notification Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for In Vitro Diagnostic Devices	Do
Draft Guidance Document for Premarket Notification Submission of Immunoglobulins A,G,M,D and E Immunoglobulin System In-Vitro Devices	Do
Draft Guidance for Premarket Notification Submission of Lymphocyte Immunophenotyping In Vitro Diagnostic Devices Using Monoclonal Antibodies	Do
Draft Guidance for Premarketing Approval Review Criteria for Premarket Approval of Estrogen or Progesterone Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding With Dextran-Coated Charcoal Separation, Histochemical Receptor Bind	Do
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification to FDA	Do
Guidance for Submission of Immunohistochemistry Applications to FDA; Final	Do
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Final	Do
Multiplex Tests for Heritable Deoxyribonucleic Acid Markers, Mutations and Expression Patterns; Draft Guidance for Industry and FDA Reviewers	Do
Points to Consider for Cervical Cytology Devices	Do
Points to Consider for Hematology Quality Control Materials	Do
Radioallergosorbent Test Methods for Allergen-Specific Immunoglobulin E (IgE) Premarket Notifications; Final Guidance for Industry and FDA	Do
Review Criteria for Assessment of Alpha-Fetoprotein In Vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies	Do
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semiautomated Chromosome Analyzers	Do
Review Criteria for Assessment of Rheumatoid Factor In Vitro Diagnostic Devices Using Engzyme-Linked Immunoassay, Enzyme Linked Immunosorbent Assay, Particle Agglutination Tests, and Laser and Rate Nephelometry	Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4692
Review Criteria for Blood Culture Systems	Do
Review Criteria for In Vitro Diagnostic Devices for Detection of Immunoglobulin Class M Antibodies to Viral Agents	Do
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies Using Indirect Immunofluorescence Assay, Indirect Hemagglutination Assay, Radioimmunoasay, and Enzyme Linked Immunosorbent Assay	Do
Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic)	Do
Review Criteria for the Assessment of Anti-Nuclear Antibodies In-Vitro Diagnostic Devices Using Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA	Do
Draft Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms	Do
Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses	Do
Assays Intended for Diagnosis, Prognosis, or Monitoring of Hepatitis C Virus Infection, Hepatitis C, or Other Hepatitis C-Associated Disease; Draft Guidance for Industry FDA	Do
Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium spp. (Tuberculosis)	Do
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to *Helicobacter Pylori*	Do
Review Criteria for Devices Assisting in the Diagnosis of *Clostriduim Difficile* Associated Diseases	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to Hepatitis B 'e'	Do
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	Do
Office of Surveillance and Biometrics	
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)	Do
Premarket Approval Application Review Statistical Checklist	Do
Statistical Aspects of Submissions to FDA: A Medical Device Perspective (Also Includes as Appendix the Article ''Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions'')	Do
Statistical Guidance for Clinical Trials of Nondiagnostic Medical Devices	Do
Statistical Guidance on Reporting Results From Studies Evaluating Diagnostic Tests; Draft	Do
Medical Device Reporting Guidance Document: Remedial Action Exemption; Final	Do
Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use	Do
Medical Device Reporting Guidance Document No. 1—Intraocular Lenses—E1996004; Final	Do
Common Problems: Baseline Reports and Medwatch Form 3500A	Do
Medical Device Reporting: An Overview; Final	Do
Instructions for Completing FDA Form 3500A With Coding Manual for Form 3500A (MEDWATCH) (Medical Device Reporting); Final	Do
MEDWATCH FDA Form 3500A For Use By User Facilities, Distributors and Manufacturers for Mandatory Reporting; Final	Do
Variance From Manufacturer Report Number Format (Medical Device Reporting Letter); Final	Do
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report (Medical Device Reporting); Final	Do
Medical Device Reporting—Alternative Summary Reporting Program; Guidance for Industry	Do
Addendum to the Instructions for Completing FDA Form 3500A With Coding Manual (MEDWATCH) (Medical Device Reporting); Final	Do
Needlesticks—Medical Device Reporting Guidance	Do
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)	Do
Guidance on Criteria and Approaches for Postmarket Surveillance	Do
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies (Food and Drug Administration Modernization Act); Final	Do
Guidance on Procedures for Review of Postmarket Surveillance Submissions (Food and Drug Administration Modernization Act); Final	Do
Guidance for Industry and FDA Staff— Safe Medical Devices Act of 1990 to Food and Drug Administration Modernization Act: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols (Food and Drug Administration Modernization Act); Final	Do
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final	Do
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket	Do
Office of Compliance	
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)	Do
Commercial Distribution/Exhibit Letter	Do
FDA Guide for Validation of Biological Indicator Incubation Time	Do
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264)	Do
General Principles of Software Validation; Draft Guidance	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance on Medical Device Tracking (Food and Drug Administration Modernization Act); Guidance for Industry and FDA Staff	Do
Compliance Program Guidance Manual: Inspection of Medical Devices; Draft	Do
Procedures for Laboratory Compliance Testing of Television Revivers—Part of Television Packet	Do
Guidance on Quality System Regulation Information for Various Premarket Submissions; Draft	Do
Surveillance and Detention without Physical Examination of Surgeons' and/or Patient Examination Gloves; Guidance for Industry	Do
Manufacturers/Assemblers of Diagnostic X-Ray Systems: Enforcement Policy for Positive-Beam Limitation Requirements in 21 CFR 1020.31 g)	Do
Guidance for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components	Do
Exemption From Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers	Do
Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi)	Do
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (FDA 89–8221)	Do
Compliance Policy Guide 7133.19: Retention of Microwave Oven Test Record/Cover Letter: August 24, 1981, Retention of Records Required by 21 CFR Part 1002	Do
Guidance for the Submission of Abbreviated Radiation Safety Reports on Cephalometric X-Ray Devices: Defined as Dental Units With an Attachment for Mandible Work That Holds a Cassette and Beam Limiting Device	Do
A Guide for the Submission of an Abbreviated Radiation Safety Report on X-Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use	Do
A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammography X-Ray Systems	Do
Compliance Program Guidance Manual: Field Compliance Testing of Diagnostic (Medical) X-Ray Equipment; Guidance for FDA Staff	Do
Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA	Do
Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Under 21 CFR 1002.10	Do
Abbreviated Report on Radiation Safety for Microwave Products (Other Than Microwave Ovens) (e.g., Microwave Heating, Microwave Diathermy, Rheumatoid Factor Sealers, Induction, Dielectric Heaters, Security Systems)	Do
Guide for Preparing Reports on Radiation Safety of Microwave Ovens	Do
Guide for Filing Annual Reports for X-Ray Components and Systems	Do
Reporting and Compliance Guide for Television Products Including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information and Guidance	Do
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (Replaces FDA 82–8127)	Do
Guide for Preparing Abbreviated Reports of Microwave and Rheumatoid Factor-Emitting Electronic Products Intended for Medical Use	Howard W. Cyr, Center for Devices and Radiological Health (HFZ–114), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–796–0297
Letter to Manufacturers and Importers of Microwave Ovens: Information Requirements for Cookbooks and User and Service Manuals	Do
Abbreviated Report on Radiation Safety of Non-Medical Ultrasonic Products	Do
Guide for Preparing Product Reports for Medical Ultrasound Products	Do
Letter to Manufacturers, Distributors and Importers of Condom Products	Do
Letter to Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt)	Do
Letter to Condom Manufacturers and Distributors	Do
Letter to Manufacturers/Repackers Using Cotton	Do
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Compliance Guide for Laser Products (FDA 86–8260)	Do
Condoms: Inspection and Sampling at Domestic Manufacturers and of All Repackers; Sampling From All Importers (Damaska Memo to Field on April 8, 1987)	Do
Dental Hand Piece Sterilization (Dear Doctor Letter)	Do
Latex Labeling Letter (Johnson)	Do
Pesticide Regulation Notice 94–4:Interim Measures for the Registration of Antimicrobial Products/ Liquid Chemical Germicides With Medical Device Use Claims Under the Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration	Do
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	
Letter to Industry, Powered Wheelchair Manufacturers From RM Johnson	Do
Hazards of Volume Ventilators and Heated Humidifiers	Do
Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals	Do
Ethylene Oxide; Ethylene Chlorohydrin; and EthyleneGlycol: Proposed Maximum Residue Limits and Maximum Levels of Exposure	Do
Letter to: Manufacturers and Users of Lasers for Refractive Surgery (Excimer)	Do
Shielded Trocars and Needles Used for Abdominal Access During Laparoscopy Surveillance and Detention Without Physical Examination of Condoms; Guidance for Industry; Draft	Do
All U.S. Condom Manufacturers, Importers and Repackagers	Do
Manufacturers and Initial Distributors of Hemodialyzers	Do
Laser Light Show Safety—Who's Responsible? (FDA 86–8262)	Do
Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Publication No. 83–8220)	Do
Letter to All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist	Do
Guide for Submission of Information on Industrial X-Ray Equipment Required Under 21 CFR 1002.10	Do
Guidance for the Submission of Cabinet X-Ray System Reports Under 21 CFR 1020.40	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)	Do
Computerized Devices/Processes Guidance—Application of the Medical Device Good Manufacturing Practice to Computerized Devices and Manufacturing Processes	Do
Guide for Preparing Product Reports for Ultrasonic Therapy Products (Physical Therapy Only)	Do
Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Unter 21 CFR 1002.10 and 1002.12 (FDA 81–8137)	Do
Guide for Preparing Annual Reports for Ultrasonic Therapy Products	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (Replaces FDA 82–8127)	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor (Replaces FDA 82–8127) Quality Control Guide for Sunlamp Products (FDA 88–8234)	Do
Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems	Do
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR Part 1002)	Do
Letter: Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products	Do
Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR Part 1002)	Do
Quality Control Practices for Compliance With the Federal Mercury Vapor Lamp Performance Standard	Do
Keeping Up With the Microwave Revolution (FDA Publication No. 91–4160)	Do
Quality Assurance Guidelines for Hemodialysis Devices	Do
Letter to Manufacturers and Importers of Microwave Ovens—Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Reporting of New Model Numbers to Existing Model Families	Do
Import: Radiation-Producing Electronic Products (FDA 89–8008)	Do
Unsafe Patient Lead Wires and Cables	Do
Application of a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device (Form FDA 3147)	Do
Letter to Trade Association: Reuse of Single-Use or Disposable Medical Devices	Do
Design Control Guidance for Medical Device Manufacturers	Do
Keeping Medical Devices Safe From Electromagnetic Interference	Do
Safety of Electrically Powered Products: Letter to Medical Devices and Electronic Products Manufacturers From Lilliam Gill and Bruce H. Burlington Correction Memo	Do
Enforcement Priorities for Single-Use Deices Reprocessed by Third Parties and Hospitals: Guidance for Industry and for FDA Staff	Do
Labeling for Electronic Anti-Theft Systems; Guidance for Industry; Final	Do
Wireless Medical Telemetry Risks and Recommendations, Guidance for Industry; Final	Do
Policy on Warning Label Required on Sunlamp Products	Do
Policy on Lamp Compatibility (Sunlamps)	Do
Office of Science and Technology	
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)	Do
Guidance on Frequently Asked Questions on Recognition of Consensus Standards (Food and Drug Administration Modernization Act)	Do
Guidance on the Recognition and Use of Consensus Standards/Appendix A (Food and Drug Administration Modernization Act)	Do
Center for Devices and Radiological Health Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition	Do
Guidance for Industry and FDA Reviewers: Guidance on Immunotoxicity Testing	Do
IV. CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)	
CATEGORY—ADVERTISING	
Promotion of Combination Oral Contraceptive Products	Nancy E. Derr, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–5400
CATEGORY—CHEMISTRY	
Documentation for Antibiotics and Other Cellular Metabolites Produced by Microorganisms Modified Using Recombinant DNA Technology	Do
CATEGORY—CLINICAL/MEDICAL	
Acne Vulgaris	Do
Ankylosing Spondylitis	Do
Antifungal	Do
Chemoprevention of Sporadic Colorectal Adenomas	Do
Clinical Evaluation of Analgesic Drug Products	Do
Clinical Evaluation of Drugs for Neuropathic Pain	Do
Clinical Evaluation of Drugs for Neuropathy	Do
Clinical Evaluation of Opiate Analgesic Drug Products	Do
Clinical Trial Design for the Treatment of Allergic Conjunctivitis	Do
Clinical Trial Design for the Treatment of Bacterial Blepharitis	Do
Clinical Trial Design for the Treatment of Bacterial Conjunctivitis	Do
Clinical Trial Design for the Treatment of Choroidal Neovascularization	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Clinical Trial Design for the Treatment of Diabetic Macular Edema	Do
Clinical Trial Design for the Treatment of Diabetic Retinopathy	Do
Clinical Trial Design for the Treatment of Dry Eye	Do
Clinical Trial Design for the Treatment of Elevated Intraocular Pressure	Do
Clinical Trail Design for the Treatment of Iritis	Do
Clinical Trail Design for the Treatment of Macular Edema (Secondary to Inflammation)	Do
Clinical Trail Design for the Treatment of Macular Edema (Secondary to a Vascular Event)	Do
Clinical Trail Design for the Treatment of Post-Cataract Inflammation	Do
Clinical Trail Design for the Treatment of Posterior Uveitis	Do
Clinical Trial Design for the Treatment of Superficial Punctate Keratitis	Do
Chemistry, Manufacturing, and Control, Preclinical, and Clinical Development of Decorporation Agents for the Treatment of Internal Radioactive Contamination	Do
Corticosteroid Induced Adrenal Suppression	Do
Development of Drugs for Chronic Obstructive Pulmonary Disease	Do
Developing Antiviral Drugs for the Treatment of Smallpox	Do
Drug-Coated Cardiovascular Stents	Do
Evaluation of New Treatments for Diabetes Mellitus	Do
Gingivitis	Do
Intraocular Pressure Lowering	Do
Oral Mucositis	Do
Patient Reported Outcomes	Do
Periodontitis	Do
Psoriasis	Do
Safety Review of Clinical Data	Do
System Lupus Erythematosus	Do
Premarketing Risk Assessment	Do
Development and Use of Risk Minimization Action Plans	Do
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment	Do
Coronary Drug-Eluting Stents	Do
Pharmacogenomic Combination Products	Do
42. Centralized Institutional Review Boards in Multi-Center Trials	Do
CATEGORY—CLINICAL/PHARMACOLOGY	
Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling	Do
Immediate Release to Modified Release Dosage Forms	Do
In Vitro Drug Metabolism/Drug Interaction—Guidance for Reviewers	Do
Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling	Do
CATEGORY—COMPLIANCE	
Describing How Positron Emission Tomography Drug Products May Comply With New Current Good Manufacturing Practice Requirements	Do
Expiration Dating of Unit-Dose Repackaged Drugs	Do
Maintaining Adequate and Accurate Records During Clinical Investigations	Do
Current Good Manufacturing Practice For Investigational New Drug and Biological Products—Phase I Testing	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
CATEGORY—ELECTRONIC SUBMISSIONS	
Standards for Clinical Data Submissions	Do
CATEGORY—GENERICS	
Abbreviated New Drug Applications Suitability Petitions	Do
Bioequivalence Studies with Clinical Endpoints for Vaginal Antifungal Drug Products	Do
Defining the Term ''Listed Drug'' With Respect to Amendments and Supplements to Abbreviated New Drug Applications and Section 505(b)(2) Applications	Do
Abbreviated New Drug Applications: Pharmaceutical Solid Polymorphism	Do
CATEGORY—GOOD REVIEW PRACTICES	
General Clinical Review Template	Do
CATEGORY—INVESTIGATIONAL NEW DRUG APPLICATION	
Consumer Product Safety Commission—Tamper Resistant Packaging for Investigational New Drugs	Do
End of Phase 2 Meetings	Do
Pediatric Safety and Efficacy Data in Investigational New Drugs	Do
Exploratory Investigational New Drugs: Preclinical and Clinical Considerations	Do
CATEGORY—LABELING	
Content and Format of the Clinical Pharmacology Section	Do
Content and Format of the Dosage and Administration Section of the Prescription Drug Labeling	Do
Content and Format of the Warnings and Precautions, Contraindications, and Boxed Warning Sections of Prescription Drug Labeling	Do
Drug Names and Dosage Forms	Do
Implementing the New Content and Format Requirements for Prescription Drug Labeling	Do
Labeling Dietary Supplements for Women Who Are or Could Be Pregnant	Do
Pregnancy Labeling Revisions	Do
Submitting Proprietary Names for Evaluation	Do
CATEGORY—OVER-THE-COUNTER	
Actual Use Trials	Do
Labeling Comprehension Studies for Over-the-Counter Drug Products	Do
Labeling for Over-the-Counter Human Drug Products	Do
Labeling of Over-the-Counter Skin Protectant Products	Do
Labeling Over-the-Counter Human Drug Products; Questions and Answers	Do
CATEGORY—PHARMACOLOGY/TOXICOLOGY	
Drug-Induced Vascular Injury	Do
CATEGORY—PROCEDURAL	
Assessment of Abuse Potential of Drugs	Do
Development of a Drug and Pharmacogenetic Test	Do
Dispute Resolution Involving Pediatric Labeling	Do
Exocrine Pancreatic Insufficiency Drug Products—Submitting New Drug Applications	Do
How to Comply With the Pediatric Research Equity Act	Do
How to Determine if Human Research With a Radioactive Drug Can Be Conducted Under a Radioactive Drug Research Committee	Do
Process for Contracts and Written Requests Under the Best Pharmaceutical for Children Act	Do
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
V. Center for Food Safety and Applied Nutrition (CFSAN)	
CATEGORY—DIETARY SUPPLEMENTS	
Labeling Dietary Supplements for Women Who Are or Could Be Pregnant	Linda Pellicore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1448, FAX 301–436–2636, *Linda.Pellicore@cfsan.fda.gov*
Dietary Supplements: 75-Day Premarket Notifications for New Dietary Ingredients	Do
Substantiation Health Claims Guidance	Do
CATEGORY—FOOD ADDITIVE SAFETY	
Final Guidance on Electronic Submissions of Food and Color Additive Petitions (Level 1)	George Pauli, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740
Presence of Unintended Varieties of Bioengineered Plant Foods in the Food Supply (Level 1)	Do
Chloropropanols Compliance Policy Guides Guidance	Do
CATEGORY—CONSTITUENT OPERATIONS	
Equivalence Level 1 Guidance	Cathy Carneval, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740
CATEGORY—OFFICE OF COMPLIANCE	
Prior Notice of Imported Food Products—Questions and Answers	May Nelson, Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740
VI. CENTER FOR VETERINARY MEDICINE (CVM)	
CATEGORY—NEW ANIMAL DRUG APPLICATIONS	
Administrative New Animal Drug Application Process (#132)	Gail Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., rm. 384, Metropark North II, Rockville, MD 20855, 301–827–1796, *gschmer1@cvm.fda.gov*
Waivers of *In Vivo* Demonstration of Bioequivalence of Certain Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles (#171)	Marilyn Martinez, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., rm. 332, Metropark North II, Rockville, MD 20855, 301–827–7577, *mmartin1@cvm.fda.gov*
CATEGORY—LABELING	
Manufacture and Labeling of Raw Meat Diets for Consumption by Dogs, Cats, and Captive Noncompanion Animal Carnivores and Omnivores (#122)	William Burkholder, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., rm. 413, Metropark North II, Rockville, MD 20855, 301–827–0179, *bburkhol@cvm.fda.gov*
Content and Format for Labeling of New Animal Drug Products (#134)	Douglass Oeller, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., rm. 324, Metropark North II, Rockville, MD 20855, 301–827–0131, *doeller@cvm.fda.gov*
CATEGORY—STATUTORY REQUIREMENTS	
Dispute Resolution—FDA Modernization Act (#79)	Marcia Larkins, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., rm. 165, Metropark North IV, Rockville, MD 20855, 301–827–4535, *mlarkins@cvm.fda.gov*
Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (#173)	David Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., rm. 390, Metropark North II, Rockville, MD 20855, 301–827–6967, *dnewkirk@cvm.fda.gov*
Chemistry, Manufacturing, and Control Changes to an Approved New Animal Drug Application or Abbreviated New Drug Applications (#83)	Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., rm. 320, Metropark North II, Rockville, MD 20855, 301–827–6956, *dbensley@cvm.fda.gov*
CATEGORY—INTERNATIONAL HARMONIZATION	

TITLE/TOPIC OF GUIDANCE	CONTACT
GL–27: Preapproval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals With Respect to Antimicrobial Resistance (#144)	William T. Flynn, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7519 Standish Pl., rm. 173, Metropark North IV, Rockville, MD 20855, 301–827–4514, *wflynn@cvm.fda.gov*
GL–28: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing (#141)	Thomas Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, rm. E375, Metropark North II, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, *tmulliga@cvm.fda.gov*
GL–33: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing (#149)	Do
GL–36: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological Acceptable Daily Intake (#159)	Do
GL–37 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing (#160)	Do
GL–38 Environmental Impact Assessments for Veterinary Medicinal Products—Phase II (#166)	Charles Eirkson, Center for Veterinary Medicine (HFV–103), Food and Drug Administration, rm. 137, Metropark North IV, 7500 Standish Pl., Rockville, MD 20855, 301–827–8561, *ceirkson@cvm.fda.gov*
CATEGORY—TARGET ANIMAL SAFETY AND EFFECTIVENESS	
Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs for Use in Animals (#123)	Linda Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., rm. N316, Metropark North II, Rockville, MD 20855, 301–827–0135, *lwilmot@cvm.fda.gov*
CATEGORY—HUMAN FOOD SAFETY	
Dioxin in Minerals Used in Animal Feed (#161)	Gloria Dunnavan, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., rm. E480, Metropark North II, Rockville, MD 20855, 301–827–1168, *gdunnava@cvm.fda.gov*
Salmonella Contamination of Feeds Compliance Policy Guide	Henry Ekperigin, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., rm. E417, Metropark North II, Rockville, MD 20855, 301–827–0174, *hekperig@cvm.fda.gov*
Bovine Spongiform Encephalopathies Compliance Program	Neal Bataller, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., rm. E441, Metropark North II, Rockville, MD 20855, 301–827–0163, *nbatalle@cvm.fda.gov*
Validation of Analytical Procedures for Type C Medicated Feed (#135)	Mary G. Leadbetter, Center for Veterinary Medicine (HFV–141), Food and Drug Administration, 7500 Standish Pl., rm. E307, Metropark North II, Rockville, MD 20855, 301–827–6964, *mleadbet@cvm.fda.gov*
VII. OFICE OF REGULATORY AFFAIRS (ORA)	
CATEGORY—COMPLIANCE AND INSPECTION	
Guidance for Investigators: Investigations Operations Manual	Michael Rogers, Division of Field Investigations (HFC–130), Food and Drug Administration, 5600 Fishers Lane, rm. 13–74, Rockville, MD 20857, 301–827–5653
CATEGORY—REGULATORY	
Guidance for Food and Drug Administration Staff: Regulatory Information Assurance; Good Practices in Converting From Paper to Electronic Processes	Paul Motise, Division of Compliance Information and Quality Assurance (HFC–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–0383
CATEGORY—COMPLIANCE AND INSPECTIONS	
Concept Paper on Bioterrorism Act Proposed Guidance to Records Access	Rudaina Alrefai, Division of Compliance Information and Quality Assurance (HFC–240), Food and Drug Administration, 1350 Piccard Dr., rm. 400L, Rockville, MD 20850, 301–827–0413
CATEGORY—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF	
21 CFR Part 58: Good Laboratory Practice, Questions and Answers	James McCormack, Division of Compliance Policy (HFC–230), Food and Drug Administration, 1350 Piccard Dr., rm. 400Z, Rockville, MD 20850, 301–827–0425

TITLE/TOPIC OF GUIDANCE	CONTACT
21 CFR Part 58: Closure of Nonclinical Laboratories	Rodney Allnutt, Division of Compliance Policy (HFC–230), Food and Drug Administration, 1350 Piccard Dr., rm. 400Y, Rockville, MD 20850, 301–827–8860
21 CFR Part 58: Comparison of the Food and Drug Administration, Environmental Protection Agency, and the Organisation for Economic and Cooperative Development Good Laboratory Practices	James McCormack, Division of Compliance Policy (HFC–230), Food and Drug Administration, 1350 Piccard Dr., rm. 400Z, Rockville MD 20850, 301–827–0425.
CATEGORY—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION INVESTIGATORS	
Auditing Nonclinical Laboratory Studies	Do
CATEGORY—GUIDANCE FOR FOOD AND DRUG ADMINISTRATION INVESTIGATORS	
Necropsy, Tissue Preparation, and Histology in Nonclinical Laboratory Studies	Do
CATEGORY—COMPLIANCE POLICY GUIDE	
Section 394.500, Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation during Design Development (CPG 7133.22)	Jeffrey Governale, Division of Compliance Policy (HFC–230), Food and Drug Administration, 1350 Piccard Dr., rm. 410A, Rockville, MD 20850, 301–827–0411
Section 300.500, Reprocessing and Reuse of Single Use Devices (CPG 7124.16)	Do
Section 310.210, Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy (CPG 7124.23)	Do
CATEGORY—REGULATORY POLICY MANUAL	
Subchapter, Disqualification of Clinical Investigators	James McCormack, Division of Compliance Policy (HFC–230), Food and Drug Administration, 1350 Piccard Dr., rm. 400Z, Rockville, MD 20850, 301–827–0425
CATEGORY—REGULATORY POLICY MANUAL SUBCHAPTER OR STAFF MANUAL GUIDE	
Untrue Statements of Material Facts	Sharon Sheehan, Division of Compliance Policy (HFC–230), Food and Drug Administration, 1350 Piccard Dr., rm. 450, Rockville, MD 20850, 301–827–0412
CATEGORY—REGULATORY POLICY MANUAL SUBCHAPTER	
Application Integrity Policy	Do
CATEGORY—REGULATORY PROCEDURES MANUAL	
Chapter 9 Imports	Carl Nielsen, Division of Import Operations (HFC–170), Food and Drug Administration, 5600 Fishers Lane, rm. 12–38, Rockville, MD 20857, 301–443–6553
VIII. OFFICE OF THE COMMISSIONER (OC)	
CATEGORY—COMPLIANCE	
Guidance for Industry Information Sheets for Institutional Review Boards and Clinical Investigators	David Lepay, Good Clinical Practice Program (HF–34), Office of Science and Health Coordination, Food and Drug Administration, 5600 Fishers Lane, rm. 9C24, Rockville, MD 20857
Guidance for Industry Computerized Systems Used in Clinical Trials	Do
CATEGORY—INSPECTION	
Guidance for FDA Staff Compliance Program 7348.811, Inspection of Clinical Investigators and Sponsor Investigators	Do

Dated: June 30, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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